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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/993,192

Applicant(s)

RHEE ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to the *H. polymorpha PRC1* gene, classified in class 536, subclass 23.74.
- II. Claims 2-5, drawn to a deletion construct for the *PRC1* gene, and cells made with the deletion construct, classified in class 435, subclass 255.6.
- III. Claims 6-8, drawn to a method for making a protein in a *PRC1* deletion strain, classified in class 435, subclass 69.1.
- IV. Claim 9, drawn to the *H. polymorpha PEP4* gene, classified in class 536, subclass 23.74.
- V. Claims 10-13, drawn to a deletion construct for the *PEP4* gene, and cells made with the deletion construct, classified in class 435, subclass 255.6.
- VI. Claims 14-16, drawn to a method for making a protein in a *PEP4* deletion strain, classified in class 435, subclass 69.1.
- VII. Claim 17, drawn to the *H. polymorpha KEX1* gene, classified in class 536, subclass 23.74.
- VIII. Claims 18-19, drawn to a deletion construct for the *KEX1* gene, and cells made with the deletion construct, classified in class 435, subclass 255.6.
- IX. Claims 20-21, drawn to a method for making a protein in a *KEX1* deletion strain, classified in class 435, subclass 69.1.

- X. Claim 22, drawn to a *PRC1 PEP4* double deletion strain, classified in class 435, subclass 255.6.
- XI. Claims 23-24, drawn to a method for making a protein in a *PRC1 PEP4* double deletion strain, classified in class 435, subclass 69.1.
- XII. Claim 25, drawn to a *PRC1 KEX1* double deletion strain, classified in class 435, subclass 255.6.
- XIII. Claims 26-28, drawn to a method for making a protein in a *PRC1 KEX1* double deletion strain, classified in class 435, subclass 69.1.
- XIV. Claim 29, drawn to a *PEP4 KEX1* double deletion strain, classified in class 435, subclass 255.6.
- XV. Claims 30-31, drawn to a method for making a protein in a *PEP4 KEX1* double deletion strain, classified in class 435, subclass 69.1.
- XVI. Claim 32, drawn to a *PRC1 PEP4 KEX1* triple deletion strain, classified in class 435, subclass 255.6.
- XVII. Claims 33-34, drawn to a method for making a protein in a *PRC1 PEP4 KEX1* triple deletion strain, classified in class 435, subclass 69.1.
- XVIII. Claims 35-38, drawn to a vector for making a *MOX3* deletion strain, and the strain made using the deletion construct, classified in class 435, subclass 255.6.
- XIX. Claims 39-41, drawn to a method for making a protein in a *MOX3* deletion strain, classified in class 435, subclass 69.1.
- XX. Claim 42, drawn to a method for popping out the *MOX3* deletion construct, classified in class 435, subclass 440.

XXI. Claim 43, drawn to a method for developing novel mutant strains in the *MOX3* deletion strain, classified in class 435, subclass 471.

The inventions are distinct, each from the other because of the following reasons:

Invention I and inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Invention I is a gene with a specific sequence, whereas invention II is a construct (and resulting strain) for the deletion of the gene and invention III is the use of a strain lacking expression of the gene to make a polypeptide. The function of I is the expression of a protein product, whereas the function of II is the abrogation of that expression and the function of III relies on the elimination of the gene's function. Therefore each invention has a separate and opposite function hence each is considered a patentably distinct invention.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (II) as claimed can be used in a materially different process such as the identification of homologs of the deleted gene (*PRCI*).

Invention IV and invention V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Invention IV is a gene with a specific sequence, whereas invention V is a construct (and resulting strain) for the deletion of the gene and invention VI is the use of a strain lacking expression of the gene to make a polypeptide. The function of IV is the expression of a protein product, whereas the function of V is the abrogation of that expression and the function of VI relies on the elimination of the gene's function. Therefore each invention has a separate and opposite function hence each is considered a patentably distinct invention.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (V) as claimed can be used in a materially different process such as the identification of homologs of the deleted gene (*PEP4*).

Invention VII and inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of

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being used together. Invention VI is a gene with a specific sequence, whereas invention VIII is a construct (and resulting strain) for the deletion of the gene and invention IX is the use of a strain lacking expression of the gene to make a polypeptide. The function of VII is the expression of a protein product, whereas the function of VIII is the abrogation of that expression and the function of IX relies on the elimination of the gene's function. Therefore each invention has a separate and opposite function hence each is considered a patentably distinct invention.

Inventions VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (VIII) as claimed can be used in a materially different process such as the identification of homologs of the deleted gene (*KEX1*).

Inventions XVIII and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (XVIII) as claimed can be used in a materially different process such as the identification of homologs of the deleted gene (*MOX3*).

The inventions of groups I-III, IV-VI, VII-IX and XVIII-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. In this instance, each group of inventions relates to a specific gene/deletion (I-III=*PRC1*, IV-VI=*PEP4*, VII-IX=*KEX1* and XVIII-XIX=*MOX3*), where each gene has a different sequence encoding a different protein with a distinct function (or lack thereof with concern to deletions). Because these genes are functionally distinct, each invention is patentably distinct from the other.

The inventions of groups X and XI, the inventions of groups XII and XIII, and the inventions of groups XIV and XV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products (X, XII or XIV) as claimed can be used in a materially different process because each double mutant strain can be used to identify functional homologs of each gene as opposed to using the strains to produce a polypeptide. In addition, the polypeptide can be made by a number of different products, including any of the single or double deletion strains as claimed.



The inventions of groups X-XV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Specifically, each strain in the different groups constitutes a different set of gene deletions, which indicates a different structure and therefore different function for each strain. Because each strain involves the deletion of a different set of genes, the inventions have different functions and are therefore patentably distinct.

Inventions XVI and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (XVI) can be used in a materially different process, such as the identification of functional homologs for each of the deleted genes. Additionally, the process of producing a polypeptide can be practiced with any of the additional deletion strain claimed.

The inventions of groups I-IX and XVIII-XIX, groups X-XV, and groups XVI-XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different

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functions and are not disclosed as capable of being used together. The inventions of groups I-IX and XVIII-XIX concern the use of single deletion strains involving specific genes, whereas the inventions of groups X-XV involve double deletions and the inventions of groups XVI-XVII involve triple deletions. The result is that each strain has a different structure and function because of the divergent sequence alterations, therefore the inventions are patentably distinct from each other.

Inventions XX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects and are not disclosed as capable of being used together. In this instance, the outcome of XX is the popping out of a construct that has been inserted into the *MOX3* gene, whereas the outcome of XXI is the generation of new mutant strains. Because the outcomes of these two inventions are different, the inventions have different effects and are therefore patentably distinct.

The inventions of groups XX-XXI and the inventions of groups I-XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Specifically, the inventions of groups XX-XXI involve the *MOX3* gene, which is structurally and functionally distinct from any of the genes or combinations of genes used in the inventions of groups I-XVIII. Because the requisite

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genes for each group of inventions are different, each group of inventions has a different function and is therefore patentably distinct.

The inventions of groups XX-XXI and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention XVIII can be used in a materially different process such as the production of a polypeptide, as opposed to the generation of a new mutation or the popping out of an expression cassette.

The inventions of groups XX-XXI and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different effects. For example, the inventions of XX and XXI are directed to the popping out of expression cassettes and the generation of novel mutations, respectively. These outcomes are distinct from the production of a polypeptide (XIX), therefore the inventions have different effects and are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. In instances where the classifications are the same, these inventions are distinct for the reasons given above and because the non-patent literature search required for each Group is not co-extensive with the non-patent literature search for the other

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described inventions hence said search would be burdensome. As a result, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson  
April 7, 2003

DAVID GUZO  
PRIMARY EXAMINER  
*David Guzo*